

In the United States Court of Federal Claims

No. 02-1211 V

(Filed April 9, 2009)

WALTER RAY GRAVES, and)
LISA GRAVES as Representatives)
of the Estate of HAYLEY NICOLE)
GRAVES, Deceased,)
Petitioners,)
v.)
SECRETARY OF THE DEPT. OF)
HEALTH AND HUMAN)
SERVICES,)
Respondent.)

ORDER

In this National Childhood Vaccine Injury Act case, petitioners Walter Ray Graves and Lisa Graves seek review of a decision by the special master denying compensation for the death of their 9-month-old daughter, Hayley Nicole Graves (“Hayley”). The death occurred on September 24, 2000.

Petitioners, by means of expert medical evidence, assert the cause of Hayley’s death to be the second administration of Prevnar, a pneumococcal vaccine she received on August 8, 2000. On August 10, 2000, Hayley suffered the onset of epilepsy partialis continua which, despite treatment with intensive medical therapies, never stopped until her death some six weeks later. Hayley’s death certificate documents the immediate cause of death as “status epilepticus” and the underlying cause as “intractable seizures.”

The evidence presented by the parties is in conflict concerning what caused the onset of seizures on August 10, 2000. Petitioner’s evidence is grounded mainly on a theory of a reaction to the August 8, 2000 administration of Prevnar vaccine causing a build-up on Interleukin-1 beta (“IL-1 beta”) in Hayley’s brain to produce the onset of seizures, together with a published postlicensure study, authored by Dr. Robert P. Wise, in 2004, listing a number of seizures, including Hayley’s, occurring after Prevnar administration. Respondent asserts the cause of Hayley’s seizures remains unknown and the evidence respondent produced discounts the possibility of IL-1 beta

build-up sufficient to cause seizures and disputes the significance of the Wise study data with respect to causation. These positions have been extensively briefed and ably presented by counsel. The special master's decision resolves the conflicting evidence by concluding that “[t]he Graveses have not established that the Prevnar vaccine caused the seizures that led to Hayley's death.” *Graves ex rel. Graves v. Sec'y of Health & Human Servs.*, No. 02-1211V, 2008 WL 4763730, at *17 (Fed. Cl. Spec. Mstr. Oct. 14, 2008).

In contrast to the conflicting evidence concerning the cause for the onset of Hayley's seizures, there appears to be agreement in the record evidence that IL-1beta in a person's system can prolong seizures. Respondent's expert, Michael H. Kohrman, M.D., Associate Professor of Pediatrics and Neurology, University of Chicago, agreed to this effect in testimony discussing petitioner's exhibits 28 and 48, “Vezzani” papers reporting tests where IL-1 beta was injected into the animal test subjects and then seizures were induced with the result that the induced seizures were prolonged. (Tr. 195, 203, 247-48.) Dr. Kohrman referred to this as a “pre-prime” of the system so that “[y]ou will produce a seizure that's longer.” (Tr. 203.)

Putting aside the issue whether the administration of Prevnar vaccine can cause the onset of seizures, the record evidence raises a question whether the IL-1 beta in Hayley's system, stemming from the vaccine administration, served to “pre-prime” her system so as to render subsequent seizures (however caused), occurring within a reasonable time period, intractable or of sufficient duration to comprise a substantial causal factor for her death. The special master's decision does not address this question.

Accordingly, prior to resolving the pending issue raised by the petitioner's Motion for Review, that is, whether to sustain or set aside the special master's seizure onset decision, it is concluded that, pursuant to 42 U.S.C. § 300aa-12(e)(2)(c), a remand to the special master is required. A supplementary decision addressing whether the intractable nature of Hayley's seizures and/or their duration comprised a substantial factor in bringing about Hayley's death and, if so, whether the reaction to Prevnar vaccine in Hayley's system, was a substantial causal factor with respect to the intractability and/or duration of the seizures she suffered. Petitioners seek compensation for Hayley's death, not for the seizures, so that even if the special master's decision that the vaccine was not proven to cause the onset of Hayley's seizures were to be sustained, there would remain for resolution the question of

vaccine causation for any increased seizure duration and intractability as related to Hayley's death. The remand proceedings will enable the special master to address fully this remaining issue. *See* 42 U.S.C. § 300aa-12(d)(3).

Thus it is **ORDERED** that:

- (1) This matter is remanded to the special master for a supplemental decision and resulting conclusion as to entitlement, as discussed above; and
- (2) On remand, the parties shall be provided the opportunity to supplement the record with any relevant additional documents and/or testimony on the question raised.

s/ James F. Merow
James F. Merow
Senior Judge